K093503

JAN - 6 2010

VELOPEX INTERNATIONAL
105 East 17th Street
St. Cloud, FL 34769
1-888-835-6739

Date: November 12, 2009

510(k) Holder: Velopex International Inc
Device Name: IntraX Film Processor
Contact: Anthony Urella
Phone: 407-957-3900
Fax: 407-957-3927
Email: tony@velopexusa.com

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510 (k) Summary

Device Name: IntraX Film Processor

- Trade Name: IntraX Film Processor
- Common Name: Automatic Film processor
- Classification name: Processor, Radiographic-Film, Automatic
- Device Class 2
- Regulation Number: 892.1900

Legally marketed device to which we are claiming equivalence:

- Air Techniques Inc. (Registered Establishment # 2428225)
  Peri-Pro Film Processor
- Air Techniques Inc. (Registered Establishment # 2428225)
  A/T 2000 Automatic Film Processor
- Dent-X Co., Model 410 Dental X-Ray Film Processor #K874118

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Anthony Urella
Vice President, Sales & Marketing
Velopex International, Inc.
105 E. 17th Street
SAINT CLOUD FL 34769

JAN - 6 2010

Re: K093503
Trade/Device Name: IntraX Film Processor
Regulation Number: 21 CFR 892.1900
Regulation Name: Automatic radiographic film processor
Regulatory Class: II
Product Code: IXW
Dated: November 12, 2009
Received: November 12, 2009

Dear Mr. Urella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K093503

Device Name: Intra·X Film Processor

Indications for Use:

The IntraX Film Processor is an automatic film processor used by dental offices to develop x-ray films. It processes all sizes of intra-oral film.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K093503